Re-evaluation Decision RVD2011-04

Iodocarb

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Re-evaluation Decision

After a re-evaluation of the material preservative iodocarb, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing iodocarb for sale and use in Canada.

An evaluation of available scientific information found that products containing iodocarb do not present unacceptable risks to human health or the environment when used according to label directions. As a condition of the continued registration of iodocarb uses, new risk-reduction measures must be included on the labels of all products. Additional data are being requested.

The regulatory approach for the re-evaluation of iodocarb was first presented in Proposed Re-evaluation Decision PRVD2010-15, *Iodocarb*, a consultation document.[1] This Re-evaluation Decision[2] describes this stage of PMRA's regulatory process for the re-evaluation of iodocarb as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-15. To comply with this decision, registrants of products containing iodocarb will be informed of the specific requirements affecting their product registration(s).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Iodocarb, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- It covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions.
- It addresses the active ingredient and the main formulation types registered in Canada.
- It is relevant to registered Canadian uses.

1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.
2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of iodocarb. In this decision, the PMRA took into account the Canadian use pattern and issues (for example, the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated iodocarb and published its conclusions in a 1997 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-15, *Iodocarb*.

What Is Iodocarb?

Iodocarb is an antimicrobial active ingredient that is used as a material preservative in textiles, adhesives, caulks, paints, latex paper coating, plastic, water-based inks, metal working fluids and a variety of consumer products (including household cleaning products). Iodocarb for use as a material preservative is applied by commercial workers during the manufacturing process. Commercial workers and homeowners can apply paint containing iodocarb using a brush, roller or an airless sprayer.

Iodocarb is also used for preservation of joinery wood products (for example, window and door frames, decorative wood) and as a sapstain control chemical. Wood uses of iodocarb are not included in this re-evaluation.

Health Considerations

Can Approved Uses of Iodocarb Affect Human Health?

Iodocarb is unlikely to affect your health when used according to the revised label directions.

People could be exposed to iodocarb by handling the biocide or by handling iodocarb-containing paint and while using iodocarb-treated products. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that iodocarb was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and similar risk-reduction measures are required.

Environmental Considerations

What Happens When Iodocarb Is Introduced into the Environment?

Iodocarb is unlikely to affect non-target organisms when used according to the revised label directions.

The USEPA concluded that iodocarb use as a material preservative is unlikely to adversely affect the environment. These conclusions apply to the Canadian situation. Based on PMRA practices, general environmental hazard label statements are required by the PMRA.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of iodocarb, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- additional personal protective equipment (PPE) to further protect workers
- prohibit the use of iodocarb-treated materials for food packaging
- limit the use of iodocarb-treated textiles to non-apparel use only
- prohibit the use of iodocarb-treated textiles in residential settings
- prohibit the use of iodocarb-treated plastic for the production of children toys and other products which may come in contact with children (for example, plastic chair, plastic bottle)
- additional good hygiene practices and proper cleaning/maintaining label statements

Environment

- advisory label statements

Appendix I lists all required label amendments, including instructions related to basic hygiene practices.

What Additional Scientific Information Is Required?

Appendix II lists all data required as a condition of continued registration under section 12 of the *Pest ControlProducts Act*. The registrants of this active ingredient are required to provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter.

Other Information

Any person may file a notice of objection[3] regarding this decision on iodocarb within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's Web site (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements below.

The labels of end-use products in Canada must be amended to include the following statements to further protect workers and the environment.

I) For material preservative uses, the following statements must be included in the **PRECAUTIONS** section:

> Workers must wear a long-sleeved shirt, long pants, chemical resistant gloves and goggles or a face shield during mixing, loading, cleanup and repair. In addition, dust filtering respirator protection is required during handling if there is a potential for dust generation.
>
> Follow manufacturer's instructions for cleaning/maintaining personal protective equipment. If no such instructions exist for washables, use detergent and hot water. Keep and wash personal protective equipment separately from other laundry.
>
> Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet.
>
> Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
>
> Users should remove personal protective equipment immediately after handling this product. Wash the outside of gloves before removing. Wash thoroughly as soon as possible.

II) For material preservative uses, the following statements must be included in the **DIRECTIONS FOR USE** section:

> DO NOT use for plastic for toys.
>
> DO NOT use for textile for apparel.
>
> DO NOT use on any fabric where prolonged skin contact may occur. Treated textiles preserved with iodocarb are not to be used in residential settings where bystanders including children may potentially contact treated textiles. This includes around homes, schools, parks, playgrounds, playing fields, public buildings or any other areas where the general public, including children, could be exposed.

III) For material preservative uses (plastic, adhesives and paper products) of iodocarb, the following label statement must be included on the **primary panel**:

> Products containing this antimicrobial pesticide are not to be used in food packaging materials or food contact products.

IV) The following statements must be included in the **ENVIRONMENTAL HAZARDS** section:

> Toxic to aquatic organisms.

V) The following label statements must be included in the **DIRECTIONS FOR USE** section:

> DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.
>
> DO NOT discharge effluents containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters.

Appendix II Additional Data Requirements

The following data are required as a condition of continued registration under section 12 of the *Pest Control Products Act*.

DACO 5.2 Use Description Scenario (iodocarb use as a material preservative in metal working fluids)

DACO 5.6 Post-application: Passive Dosimetry Data (for workers handling iodocarb-treated metal working fluids and/or involved in maintenance/clean-up activities)